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HEADLINE: Diabetes Expert Raised Issue Of Avandia Heart Risk in 2000

BYLINE: By Anna Wilde Mathews and Jeanne Whalen

BODY:

A leading diabetes expert wrote to the Food and Drug Administration in 2000, raising concerns about a potential heart risk tied to the diabetes drug Avandia.

But, underscoring the debate now playing out over the safety of the GlaxoSmithKline PLC medication, he says he isn't sure if the worries he raised then are valid.

On Monday, the New England Journal of Medicine released an analysis by Cleveland Clinic cardiologist Steven Nissen linking Avandia to a potential risk of heart attacks. Glaxo disagrees with the finding, which it says is contradicted by data from sources the British company considers stronger. Congressional investigators are examining the FDA's and the company's handling of the drug.

John Buse, a professor at the University of North Carolina who is president-elect of the American Diabetes Association, told the FDA seven years ago that he was concerned about a "worrisome trend in cardiovascular deaths and severe adverse events" in the data submitted to win FDA approval for Avandia. He also warned of "rampant abuse of clinical-trial data" by then-maker SmithKline Beecham, saying the company had "overstated the safety of the drug with respect to cardiovascular issues."

Dr. Buse's letter noted that at the time, he was consulting for the makers of two competing diabetes drugs, Actos and Rezulin, and had consulted in the past for SmithKline Beecham. Rezulin was withdrawn from the market soon after the letter was written, over concerns about liver failure, and the letter responded to worries about the safety of the drugs. Dr. Buse says now that he doesn't believe his consulting relationships affected his views.

Dr. Buse yesterday said he believes it is "too soon to tell" for sure if there is a heart-attack risk, and he hopes the FDA will soon reveal data that the agency has said point away from that possibility.

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Also, an editorial in the medical journal Lancet argued that it "would be premature to overinterpret" Dr. Nissen's analysis.

Glaxo's chief executive, J.P. Garnier, yesterday said he thinks there has been "an overreaction to a publication which was actually quite sensibly written," referring to Dr. Nissen's analysis. A Glaxo spokeswoman said the company was aware of Dr. Buse's 2000 letter, and "we strongly disagree with the content of the letter, which we found to be based on incomplete and in places inaccurate information."

The company, which received a warning letter from the FDA in 2001 complaining that it had minimized a risk in its promotion, said "action was taken at the time to ensure representatives of the company were accurately reflecting the label for the product in any commercial activity."

An FDA spokeswoman said the agency at the time "provided a general response thanking him for the letter" and also sent Dr. Buse copies of FDA news releases that explained the agency's actions.

Dr. Nissen said his article pointed out the limits of his analysis, but he added that he "thinks the findings are going to hold up very well in the long run."

Earlier this week, the Senate Finance Committee Chairman, Montana Democrat Max Baucus, and Sen. Charles Grassley, an Iowa Republican, sent a letter to Glaxo mentioning "reports that GSK employees silenced one or more medical professionals who attempted to speak out" about potential heart risks from Avandia.

The company called the suggestion "absolutely false."

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